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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	**Friedel Frauendorfer**
Application No.:	**09/719258**
Filed:	**April 13, 2000**
For:	**ORAL DOSAGE FORM**
Examiner:	**Sharmila S. Gollamudi**
Group Art Unit:	**1616**

Mail Stop APPEAL BRIEF - PATENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Docket No.: H01.2I-9587-US01

TRANSMITTAL LETTER

1. In regard to the above-identified application, in addition to this **2** page transmittal letter, we are submitting the attached:
17 Pg Appeal Brief in Triplicate (1 original and 2 Copies); and Return Postcard.

2. With respect to fees:
☑ No additional fee is required.
☐ Attached is check(s) in the amount of $
☑ Charge any fee deficiency to our Deposit Account No. 22-0350.

3. **CONDITIONAL PETITION FOR EXTENSION OF TIME**
This conditional petition is being filed along with the papers identified in Item 1 above and provides for the possibility that Applicant has inadvertently overlooked the need for a petition and fee for extension of time or for a petition and fee for any other matter petitionable to the Commissioner as required. If any extension of time for the accompanying response is required or if a petition for any other matter is required, by petitioner, Applicant requests that this be considered a petition therefor.

4. Notwithstanding paragraph 2 above, if any additional fees associated with this communication are required and have not otherwise been paid, including any fee associated with the Conditional Petition for Extension of Time, or any request in the accompanying papers for action which requires a fee as a petition to the

Commissioner, please charge the additional fees to Deposit Account No. 22-0350. Please charge any additional fees or credit overpayment associated with this communication to the Deposit Account No. 22-0350.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: July 8, 2004

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Certificate Under 37 CFR 1.10: I hereby certify that this Transmittal Letter and the paper(s) as described herein, are being deposited in the U.S. Postal Service, as EXPRESS MAIL, Label No. EV547670673US, addressed to Mail Stop APPEAL BRIEF - PATENT, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on July 8, 2004.

Mary C. Granger

PATENT

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In re Application of:	**Friedel Frauendorfer**
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BRIEF ON APPEAL

This is a Brief on Appeal for the above-identified application in which claims 1 – 14 were finally rejected in an Office Action mailed October 29, 2003. A Notice of Appeal was filed January 27, 2004. The fees required under 37 CFR § 1.17(c) and any required petition for extension of time for filing this brief are addressed in the accompanying Transmittal of Appeal Brief. This brief is transmitted in triplicate in accordance with 37 CFR § 1.192(a).

(1) Real Party in Interest

The Application is assigned to Meduna Arzneimittel GmbH, a corporation having its principal place of business at Ernst-Grote-Strasse 23, D-30916 Isernhagen/Germany.

(2) Related Appeals and Interferences

No related appeals or interferences are pending.

(3) Status of Claims

Claims 1 – 14 are the subject of this appeal. No other claims are pending.

(4) Status of Amendments

No Amendment has been filed subsequent to the Final Office Action dated 10/29/03. Applicant notes that the Final Office Action indicated that the Information Disclosure Statement filed August 12, 2003 failed to include an English abstract of a cited foreign document. Applicant's representative spoke with the Examiner on March 4, 2004 to discuss the IDS. It was discovered that the IDS erroneously cited DE 0240581 due to a typographical error. The IDS was intended to cite EP 0240581. The Examiner indicated that the English abstract of EP 0240581 has been considered.

(5) Summary of Invention

The present invention relates to an oral dosage form for food, food supplements and dietics (see page 1, lines 1 – 2). For example, the oral dosage form provides positive effects for the metabolism of fat and intestinal inflammations (see page 3, lines 19 – 21).

In one embodiment, the invention comprises polyunsaturated fatty acids in a gelatine capsule, the gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of the polyunsaturated fatty acids (see page 2, lines 11 – 12 and 17 – 19). Because peroxidation of the polyunsaturated fatty acids is inhibited by the xylose-hardened capsule, antioxidants are not required to be mixed into the fatty acids (see page 2, lines 14 – 16). The Application provides tables comparing the peroxide values at given time intervals between xylose-hardened and non-hardened 500 mg perilla oil capsules (see page 4).

Polyunsaturated fatty acids may include omega-3 polyunsaturated acids with a high content of alpha linolenic acid, such as perilla oil; fish oil; linseed oil; and gamma-linolenic acid. (see page 3, lines 4 – 6).

Xylose-hardening provides the gelatine capsule with a retarded opening time of 45 minutes or more (see page 2, lines 12 – 13). By providing an undisturbed release of the polyunsaturated fatty acids in the intestine after passing the stomach, unpleasant smells and flatulence may be prevented (see page 2, lines 20 – 22).

Xylose-hardening of the gelatine capsule may be achieved by spraying the capsule with a solution comprising xylose, ethanol and water for a predetermined time interval. The capsules may be heated during spraying. After spraying, the capsules may be heat-treated for a predetermined time interval, causing the xylose to react with the gelatin to provide a cross-linking (see page 4, lines 2 – 9).

(6) Issues

Issue 1: Whether claims 1 – 4, 6 – 9 and 11 – 14 are patentable under 35 USC § 103(a) over Cade et al. (WO 97/04755; hereinafter "Cade") in view of XP-002143507 (hereinafter "XP").

Issue 2: Whether claims 1 – 7 and 9 – 14 are patentable under 35 USC § 103(a) over Yajima (US 4525306) in view of Cade.

(7) Grouping of Claims

With respect to Issue 1:

Claims 1, 2, 4, 7, 8, 11 stand or fall together.

Claims 3 and 9 stand or fall together.

Claim 6 stands or falls alone.

Claim 12 stands or falls alone.

Claim 13 stands or falls alone.

Claim 14 stands or falls alone.

With respect to Issue 2:

Claims 1, 2, 5, 7, 10 stand or fall together.

Claims 3 and 9 stand or fall together.

Claim 4 stands or falls alone.

Claim 6 stands or falls alone.

Claim 12 stands or falls alone.

Claim 13 stands or falls alone.

Claim 14 stands or falls alone.

(8) Argument

Issue 1: Whether claims 1 – 4, 6 – 9 and 11 – 14 are patentable under 35 USC § 103(a) over Cade et al. (WO 97/04755; hereinafter "Cade") in view of XP-002143507 (hereinafter "XP").

Appellant asserts that Cade in view of XP does not teach all of the limitations of the rejected claims, and that the Examiner has impermissibly relied on possible inherency and hindsight in making the rejections under 35 USC § 103. Further, the claimed invention provides unexpected results that are not suggested by Cade and XP.

a) The applied references do not teach all of the claim limitations.

Appellant asserts that neither Cade nor XP teaches "a gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids" as recited in independent claim 1 and similarly recited in independent claim 11. Neither Cade nor XP even mentions a problem of peroxidation. Further, Appellant asserts that there is no motivation to combine Cade with XP for the purpose of producing the claimed invention, and that even in combination the cited references would not have provided a reasonable expectation of success of producing the claimed invention.

XP discloses a lipid formulation for treating inflammatory bowel disease. The composition may include fats and oils containing omega-3-polyenoic fatty acid and an extract of leaves of perilla. The composition may be charged into a gelatin soft capsule. See Abstract. The Examiner admits that XP does not disclose the composition of the gelatin capsule (see Paper No. 16, page 3, line 6).

Cade discloses hard gelatin capsules with reduced water permeability. The objective of Cade is to **reduce the risk of destabilization** of hard gelatin capsule content **due to humidity**. Cade discusses at length the problems of moisture associated with gelatin capsules (see page 1, line 9 – page 3, line 30). Water transport and hygroscopicity are the only problems that Cade discusses or is concerned with solving.

Cade discloses that water transport may be reduced by laminating a gelatin capsule with a

polymer layer, or by adding at least one polyol to the gelatin formulation during production (see page 4, lines 1 – 7). Suitable polyols to be used during gelatin production include sugars, sugar alcohols and other sugar substitutes, as well as polyvinyl alcohol and structural analogues thereof (see page 6, lines 15 – 25).

Thus, Cade teaches adding a polyol to the gelatin in order to reduce water permeability.

Even assuming for the sake of argument that there is motivation to combine Cade with XP, the combination would teach a composition of omega-3-polyenoic fatty acid and an extract of leaves of perilla within a gelatin capsule that has been treated with a polyol to reduce water permeability. A person of ordinary skill in the art attempting to reduce peroxidation of polyunsaturated fatty acids within a gelatin capsule would not be lead to the combination of the Cade gelatin capsule with the XP composition, as neither reference even mentions the peroxidation of fats.

Neither Cade nor XP makes any disclosure as to the problem of **peroxidation**, or the **prevention of peroxidation** of polyunsaturated fatty acids within a gelatin capsule.

Therefore, the cited references do not teach or suggest all of the limitations of independent claims 1 or 11.

b) The Examiner has impermissibly relied on possible inherency and hindsight.

Although Cade does not mention the peroxidation of fatty acids, the Examiner has applied Cade as if inherently discloses a gelatin capsule sufficiently treated to prevent peroxidation, and has argued that prevention of the presence of oxygen is *implicit* in the prevention of moisture penetration in the Cade capsule (see Paper No. 16, page 4, lines 4 - 6). The Examiner has also argued that Cade's disclosure of chemical degradation of the substance within the capsule due to moisture reads on the problem of peroxidation of fatty acids (see Paper No. 16, page 4, lines 1 – 4).

First, Appellant asserts that consideration of an inherent quality is relevant only to anticipation, not obviousness (see *Jones v. Hardy*, 230 USPQ 1021 (Fed. Cir. 1984)).

Second, Appellant respectfully disagrees with both of the Examiner's contentions. As to chemical degradation, Cade states, "***Moisture take-up*** by fills from capsules or more frequently

from the environment by permeation may affect the properties of powder fills: they may agglomerate or, more seriously, degrade chemically for example by hydrolysis" (page 2, lines 16 – 20 (emphasis added)). Thus, the teaching in Cade of chemical degradation is limited to degradation caused by moisture. Cade does not disclose or suggest any inhibition of peroxidation.

As to the possibility of a Cade capsule inherently resisting the penetration of oxygen, the Examiner has argued that because Cade improves the protection of fills from atmospheric water vapor, which is a liquid suspended in air, the capsules inherently prevent oxygen (i.e. air) from entering the capsules. (See e.g. Paper 16, page 5, lines 4 – 10). Appellant asserts that the Examiner has provided absolutely no prior art reference which supports the assumption that a substance which resists vapor penetration will automatically and inherently resist oxygen penetration.

Appellant further asserts that a material with improved resistance to water permeability does not necessarily have an inherent improved resistance to air permeability. Water molecules differ from oxygen molecules in many ways, including physical size and the state of the matter. Liquid water is in a different state than gaseous oxygen. In the more specialized field of barrier polymers:

> "Some polymers show excellent gas barrier properties but poor water barrier rates...; and others are poor gas barriers but good water barriers...."

Steingiser et al. "Barrier Polymers." *Kirk-Othmer Concise Encyclopedia of Chemical Technology*. New York: John Wiley & Sons, Inc., 1985. A copy of this document is attached hereto (see page 148, column 2, lines 7 – 12).

Consequently, the Examiner has shown no reasonable basis upon which a skilled person, seeking to solve a peroxidation problem could expect to succeed using Cade's capsules.

Appellant asserts that reading a problem of peroxidation into the Cade disclosure constitutes an impermissible use of hindsight based from Appellant's disclosure. Obviousness cannot be established by hindsight combination to produce the claimed invention (see *In re Gorman*, 18 USPQ2d 1885 (Fed.Cir.1991)). It is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination.

Further, Appellant asserts that xylose hardening a gelatine capsule to an extent sufficient

to inhibit peroxidation of polyunsaturated fatty acids does not necessarily reduce water permeability. Appellant's own tests show that in at least one embodiment of an inventive xylose treated capsule sufficient to inhibit peroxidation of polyunsaturated fatty acids, when stored for 6 months at 30°C temperature and 60% humidity the capsule may become dark and begin to lose its shape due to moisture. For this reason, the Appellant's commercial product is labeled, "Keep in a dry place." (See Amendment dated August 7, 2003, page 6, lines 6 – 12). Thus, the gelatin capsule as claimed herein does not necessarily inhibit moisture permeation as taught by Cade.

The Examiner has erred by reading a problem of peroxidation into the Cade disclosure and relying on possible inherency with no support in the record while making a rejection under 35 USC § 103.

c) Unexpected results

Appellant asserts that the Examiner has not presented a *prima facie* case of obviousness for at least the reasons discussed in the previous sections. However, even if it is found that the Examiner has established *prima facie* obviousness by combining Cade and XP, the unexpected results of peroxidation prevention presented in the application are sufficient to overcome the Examiner's showing. The presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

Based upon the teachings of Cade and XP, the use of Cade's hard gelatin capsules with XP's lipid formulation would not be expected to provide any benefit over XP's soft gelatin capsules in the prevention of peroxidation of the lipids because Cade and XP are silent as to the peroxidation of fatty acids. Thus, the prevention of peroxidation according to the claimed invention is a result that would not have been expected in the cited prior art.

"Evidence of unexpected properties may be in the form of a direct or indirect comparison of the claimed invention with the closest prior art which is commensurate in scope with the claims." See *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)

XP discloses a lipid formulation and Cade does not. Therefore, as to peroxidation of fatty acids, XP is the closest prior art to the claimed invention.

The Application at page 4 includes two tables directly comparing the peroxide values at

given time intervals between xylose-hardened 500 mg perilla oil capsules according to the claimed invention and prior art non-hardened 500 mg perilla oil capsules, which are considered by Appellant to be representative of XP's soft gelatin capsules. The xylose-hardened capsules clearly provide a significant, practical advantage over the prior art capsules, and the inhibition of peroxidation of fatty acids would have been unexpected even in light of Cade and XP.

(d) Summary and dependent claims

Appellant has asserted that the Examiner has not presented all of the limitations of independent claims 1 and 11 in the prior art, and that the Examiner has erroneously relied on hindsight and possible inherency in making an obviousness rejection. Further, the application teaches results that would have been unexpected from the teachings of the cited references. For these reasons, Appellant respectfully submits that independent claims 1 and 11 are not made obvious by Cade in view of XP.

"Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious." *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987). Therefore, Appellant asserts claims 2 – 4, 6 and 12 – 14, which depend from claim 1, and claims 7 – 10, which depend from claim 11, are also not made obvious by Cade in view of XP for at least the reasons asserted above in addition to the reasons discussed below.

Dependent claims 3 and 9 stand or fall together

Neither Cade nor XP discloses a gelatine capsule having a retarded release time of more than 45 minutes, as recited in dependent claims 3 and 9. Cade in fact discloses that rupture or dissolving times of the capsules treated with the polyol additive *decreases* with increasing content of the additive (see page 6, lines 15 – 21). Thus, Cade teaches away from claims 3 and 9.

Dependent claim 6 stands or falls alone

With respect to claim 6, neither Cade nor XP discusses antioxidants or the problem of peroxidation. Thus, no basis in the record has established suggesting the intentional exclusion of

antioxidants. Therefore, claim 6 is not suggested by the cited prior art.

Dependent claims 12 – 14 each stand or fall alone

With respect to claims 12 – 14, Cade discloses coating a gelatin capsule using "conventional techniques for capsule or tablet coating." See page 4, lines 15 – 16 and 27 – 29. However, Cade does not recite "spraying the capsule with xylose" as contained in claim 12; "heat treatment for a predetermined time interval" as contained in claim 13; or "a reaction between the xylose and gelatine capsule to provide a cross-linking" as contained in claim 14, and the Examiner has not applied references teaching these limitations. Therefore, claims 12 – 14 are not taught by the cited prior art.

Issue 2: Whether claims 1 – 7 and 9 – 14 are patentable under 35 USC § 103(a) over Yajima (US 4525306) in view of Cade.

Appellant asserts that Yajima in view of Cade does not teach all of the limitations of the rejected claims, and that the Examiner has impermissibly relied on possible inherency and hindsight in making the rejections under 35 USC § 103. Further, the claimed invention provides unexpected results that are not suggested by Cade and XP.

a) The applied references do not teach all of the claim limitations.

Appellant asserts that neither Yajima nor Cade discloses or suggests "a gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids" as recited in independent claim 1 and similarly recited in independent claim 11. Further, Appellant asserts that there is no motivation to combine Cade and Yajima to arrive at the claimed invention, as Yajima teaches away from the claimed invention.

As discussed above, Cade discloses hard gelatin capsules with reduced water permeability to reduce the **risk of destabilization** of contents **due to humidity**.

Yajima discloses soft capsules containing oils and fats, and the prevention of oxidation of oils and fats by the **addition of an antioxidant**, such as butylated hydroxyanisole, butylated

hydroxytoulene and tocopherol (see column 1, lines 6 – 20), or a component derived from herb spices (see column 2, lines 53 – 66). Thus, Yajima teaches the reduction of oxidation of oils and fats by the use of **chemical antioxidant preservatives** mixed into the oil and fat composition contained within a soft gelatin capsule.

One of ordinary skill in the art viewing Yajima and Cade would not be motivated to use the capsule of Cade with the composition of Yajima for the purpose of oxidation prevention, as Yajima already solves the oxidation problem by teaching a method of inhibiting peroxidation utilizing chemical additives. Thus, Yajima teaches away from the claimed invention. Further, even if the references were combined, there is no teaching that the Cade capsule would provide any benefit in the prevention of oxidation.

Appellant's own disclosure discusses the use of antioxidants as a prior art method of reducing oxidation (page 1, lines 6 – 11). The final sentence of Appellant's disclosure on page 5 states that the finished xylose-hardened capsule inhibits the peroxidation of fatty acids so that the addition of antioxidants is unnecessary.

Although Yajima discloses a problem of peroxidation, the only suggested method of solving the problem is the use of chemical antioxidants. Thus, Yajima adds nothing with respect to the teaching of gelatin capsules provided by Cade. Therefore, Yajima and Cade do not teach "a gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids."

b) The Examiner has impermissibly relied on possible inherency and hindsight.

Similarly to the Examiner's previous rejection over Cade in view of XP, the Examiner argues that Cade's disclosure of chemical degradation due to moisture reads on the problem of peroxidation of fatty acids, and that reduced oxygen permeability is implicit in the Cade capsule.

First, Appellant asserts that consideration of an inherent quality is relevant only to anticipation, not obviousness (see *Jones v. Hardy*, 230 USPQ 1021 (Fed. Cir. 1984)).

Second, Appellant respectfully disagrees with both of the Examiner's contentions. As to chemical degradation, Cade states, "***Moisture take-up*** by fills from capsules or more frequently from the environment by permeation may affect the properties of powder fills: they may

agglomerate or, more seriously, degrade chemically for example by hydrolysis" (page 2, lines 16 – 20 (emphasis added)). Thus, the teaching in Cade of chemical degradation is limited to degradation caused by moisture. Cade does not disclose or suggest any inhibition of peroxidation.

As to the possibility of a Cade capsule inherently resisting the penetration of oxygen, Appellant asserts that the Examiner has provided absolutely no prior art reference which supports the assumption that a substance which resists vapor penetration will automatically and inherently resist oxygen penetration.

Appellant further asserts that a material with improved resistance to water permeability does not necessarily have an inherent improved resistance to air permeability. Water molecules differ from oxygen molecules in many ways, including physical size and the state of the matter. Liquid water is in a different state than gaseous oxygen. In the more specialized field of barrier polymers:

> "Some polymers show excellent gas barrier properties but poor water barrier rates...; and others are poor gas barriers but good water barriers...."

Steingiser et al. "Barrier Polymers." *Kirk-Othmer Concise Encyclopedia of Chemical Technology*. New York: John Wiley & Sons, Inc., 1985. A copy of this document is attached hereto.

Consequently, the Examiner has shown no reasonable basis upon which a skilled person, seeking to solve a peroxidation problem could expect to succeed using Cade's capsules.

Appellant asserts that reading a problem of peroxidation into the Cade disclosure constitutes an impermissible use of hindsight based from Appellant's disclosure. Obviousness cannot be established by hindsight combination to produce the claimed invention (see *In re Gorman*, 18 USPQ2d 1885 (Fed.Cir.1991)). It is the prior art itself, and not the applicant's achievement, that must establish the obviousness of the combination.

Further, Appellant asserts that xylose hardening a gelatine capsule to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids does not necessarily reduce water permeability. Appellant's own tests show that in at least one embodiment of an inventive xylose treated capsule sufficient to inhibit peroxidation of polyunsaturated fatty acids, when stored for 6 months at 30°C temperature and 60% humidity the capsule may become dark and begin to lose

its shape due to moisture. For this reason, the Appellant's commercial product is labeled, "Keep in a dry place." (See Amendment dated August 7, 2003, page 6, lines 6 – 12). Thus, the gelatin capsule as claimed herein does not necessarily inhibit moisture permeation as taught by Cade.

The Examiner has erred by reading a problem of peroxidation into the Cade disclosure and relying on possible inherency with no support in the record while making a rejection under 35 USC § 103.

c) Unexpected results

Appellant asserts that the Examiner has not presented a *prima facie* case of obviousness for at least the reasons discussed in the previous sections. However, even if it is found that the Examiner has established *prima facie* obviousness by combining Yajima and Cade, the unexpected results of peroxidation prevention using a xylose-hardened gelatine capsule presented in the application are sufficient to overcome the Examiner's showing. The presence of a property not possessed by the prior art is evidence of nonobviousness. *In re Papesch*, 315 F.2d 381, 137 USPQ 43 (CCPA 1963).

The combination of the teachings of Yajima and Cade would prevent the peroxidation of fatty acids using chemical antioxidants. If the combination were made without including the Yajima chemical antioxidants, the resulting product would be expected to be vulnerable to peroxidation of the fatty acids. The invention of claim 1 prevents peroxidation of fatty acids *without* using chemical antioxidants. Thus, in addition to being superior to Yajima and Cade, claim 1 presents results that would be unexpected in light of Yajima and Cade.

(d) Summary and dependent claims

Appellant has asserted that the Examiner has not presented all of the limitations of independent claims 1 and 11 in the prior art, and that the Examiner has erroneously relied on hindsight and possible inherency in making an obviousness rejection. Further, the application teaches results that would have been unexpected from the teachings of the cited references. For these reasons, Appellant respectfully submits that independent claims 1 and 11 are not made

obvious by Yajima in view of Cade.

"Dependent claims are nonobvious under section 103 if the independent claims from which they depend are nonobvious." *Hartness Int'l, Inc. v. Simplimatic Eng'g Co.*, 819 F.2d 1100, 1108, 2 USPQ2d 1826, 1831 (Fed. Cir. 1987). Therefore, Appellant asserts claims 2 – 6 and 12 – 14, which depend from claim 1, and claims 7 – 10, which depend from claim 11, are also not made obvious by Yajima in view of Cade for at least the reasons asserted above in addition to the reasons discussed below.

Dependent claims 3 and 9 stand or fall together

Neither Yajima nor Cade discloses a gelatine capsule having a retarded release time of more than 45 minutes, as recited in dependent claims 3 and 9. Cade in fact discloses that rupture or dissolving times of the capsules treated with the polyol additive decreases with increasing content of the additive (see page 6, lines 15 – 21). Thus, Cade teaches away from claims 3 and 9.

Dependent claim 4 stands or falls alone

Yajima discloses that fatty acids may be effective in the prevention and treatment of hardening of arteries and heart diseases (see column 2, lines 11 – 13 and 25 – 31). However, neither Yajima nor Cade discloses a dosage form that is operative against diseases of metabolism of fat and/or against intestinal inflammations, as recited in claim 4.

Dependent claim 6 stands or falls alone

Claim 6 recites a dosage form wherein no antioxidants are added to the polyunsaturated fats. Yajima teaches the use of axtioxidants and therefore teaches away from claim 6.

Dependent claims 12 – 14 each stand or fall alone

With respect to claims 12 – 14, Cade discloses coating a gelatin capsule using "conventional techniques for capsule or tablet coating." See page 4, lines 15 – 16 and 27 – 29. However, Cade does not recite "spraying the capsule with xylose" as contained in claim 12; "heat treatment for a predetermined time interval" as contained in claim 13; or "a reaction between the xylose and gelatine capsule to provide a cross-linking" as contained in claim 14.

Conclusion

Based on at least the foregoing remarks, Appellant believes that the Examiner has erred in maintaining the rejections under 35 USC § 103 because:

1. the Examiner has not shown all of the limitations of the claims in the prior art;
2. the Examiner has relied on inherency in making rejections under 35 USC § 103;
3. the Examiner has used impermissible hindsight in reading the problem of peroxidation of fatty acids into the Cade disclosure ; and
4. the Examiner has not considered the unexpected results presented in the application.

Therefore, the Board is respectfully requested to reverse the rejections under 35 USC § 103.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: 7/8, 2004

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(9) Appendix

1. An oral dosage form for food, food supplements and dietetics comprising polyunsaturated fatty acids in a gelatine capsule, the gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids.

2. The dosage form as recited in claim 1 comprising omega-3 polyunsaturated fatty acids with a high content of alpha linolenic acid.

3. The dosage form as recited in claim 1, wherein said gelatine capsule has a retarded release time of more than 45 minutes.

4. The dosage form according to claim 1, wherein said dosage form is operative against diseases of metabolism of fat and/or against intestinal inflammations.

5. The dosage form according to claim 1, wherein the gelatine capsule comprises one ingredient selected from the group consisting of fish oil, linseed oil and gamma linolenic acid.

6. The dosage form according to claim 1, wherein no antioxidants are added to the polyunsaturated fatty acids.

7. The method as recited in claim 11, wherein said gelatine capsule comprises polyunsaturated fatty acids with a high content of alpha linolenic acid.

8. The method as recited in claim 7, wherein said gelatine capsule comprises perilla oil.

9. The method according to claim 11, wherein said gelatine capsule has a retarded release time of more than 45 min.

10. The method according to claim 11, wherein said gelatine capsule comprises an ingredient selected from the group consisting of fish oil, linseed oil and gamma linolenic acid.

11. A method for slowing down peroxidation of polyunsaturated fatty acids used for food, food supplement and dietetics comprising the step of utilizing a gelatine capsule, the gelatine capsule being xylose-hardened to an extent sufficient to inhibit peroxidation of polyunsaturated fatty acids.

12. The dosage form as recited in claim 1, wherein the gelatine capsule is formed by a process including spraying the capsule with xylose.

13. The dosage form as recited in claim 12, wherein the process further comprises heat treatment for a predetermined time interval.

14. The dosage form as recited in claim 13, wherein the process further comprises a reaction between the xylose and gelatine capsule to provide a cross-linking.

ing it into the desired substance. Barium sulfide is handled in the form of an aqueous solution and only rarely is separated as a solid.

Barium sulfite, $BaSO_3$, occurs as colorless cubic (or hexagonal) crystals, with solubility 0.02 g/100 g H_2O at 0°C.

Barium titanate, $BaTiO_3$ (mp, ca 1625°C), has both ferroelectric and piezoelectric properties and is used in sonar equipment, in phonograph cartridges, capacitators, and other electronic equipment.

TRUMAN KIRKPATRICK
The Sherwin-Williams Company

F.B. Fulkerson, "Barium," preprint from Bureau of Mines Bulletin 667, *Mineral Facts and Problems*, U.S. Department of the Interior, Bureau of Mines, Superintendent of Documents, Washington, D.C., 1975.

S.K. Haines, "Barite," preprint from Bureau of Mines *Minerals Yearbook 1976*, U.S. Department of the Interior, Bureau of Mines, Superintendent of Documents, Washington, D.C.

R.B. Reznik and H.D. Toy, Jr., *Source Assessment: Barium Chemicals*, EPA MRC-DA-530, Contract No. 68-02-1874, Office of Research and Development, U.S. Environmental Protection Agency, Washington, D.C., Feb. 1976.

D.A. Brobst, "Barite" in D.A. Brobst and W.P. Pratt, eds., *United States Mineral Resources, U.S. Geological Survey Professional Paper 820*, U.S. Government Printing Office, Washington, D.C., 1973, pp. 75–84.

BARRIER POLYMERS

The general theory of permeation of a gas or liquid through a polymer matrix states that the permeation rate is the product of a diffusion term and a solubility constant of the gas–liquid in the polymer matrix, each of which is often independent of the other. The process of permeation through a polymeric barrier involves four steps: absorption of the permeating species into the polymer wall; solubility in the polymer matrix; diffusion through the wall along a concentration gradient; and desorption from the outer wall. In order to be a good barrier polymer, the material must have some degree of polarity such as contributed by the nitrile, ester, chlorine, fluorine, or acrylic functional groups; high chain stiffness; inertness; close chain-to-chain packing by symmetry, order crystallinity, or orientation; some bonding or attraction between chains; high glass-transition temperature T_g. Permeability also is affected by fillers and additives, moisture content, temperature, thickness, and molecular structure of permeating gas or liquid.

Measurement of Barrier Properties

The most common method of measuring gas permeation uses a Dow Permeation Cell. Water permeation through a polymer generally is measured by gravimetric weight loss of a sealed water-filled container made from the test polymer or by gravimetric weight loss of a special metal cup (such as the Paine cup) which uses the test polymer as a lid. Organic-liquid permeation usually is measured by using a filled molded container made of the test polymer and noting gravimetric weight loss. In all measurements of gas or liquid permeation, it is necessary to allow time for equilibrium rates to become established or erroneous values will be obtained.

A high barrier polymer can be defined as one that exhibits a high resistance to molecular flow of a permeating agent or agents through the polymer matrix. To qualify as a truly high barrier polymer, the following limits of permeation should apply based on studies of the packaging of products that are sensitive to gases, liquids, or organic-vapor diffusion: a gas transmission of not more than 10 cm^3 of oxygen per 0.025 nm of polymer per 645 cm^2 (10 $in.^2$) of surface per day per 101 kPa (760 mm Hg) driving force at 23°C and humidity conditions of use; water permeation of not more than 7 g per 0.025 mm per 645 cm^2 per day in direct contact with water at 38°C and with low rh air circulating on the downstream side of the barrier; and less than 5% loss of an organic substance by absorption and/or diffusion from a solution of the substance in contact with the polymer for a period of at least 6 months at 23°C (or equivalent).

Table 1 lists currently available polymers meeting the requirements of high barrier polymers and compares their permeation rates for oxygen, carbon dioxide, water, and organic compounds. There are also several well-known polymers that come close to meeting the limits set for gas and water permeation and that can be considered as moderate barrier polymers: nylon-6; nylon-6,6; Delrin, Penton, poly(vinyl fluoride), poly(methyl methacrylate); nylon-11; and XT Polymer. Some polymers show excellent gas barrier properties but poor water barrier rates, eg, poly(vinyl alcohol) (dry) and cellophane (dry-uncoated); and others are poor gas barriers but good water barriers, eg, high density polyethylene, polypropylene, Teflon (polytetrafluoroethylene), polybutene, low density polyethylene, Surlyn ionomer, and butyl rubber.

Absorption from Dilute Solutions

A property related to barrier properties, but more subtle, is that of the absorption by the polymer of the molecules of a solution in contact with it. In many cases, these can be large bulky organic molecules, and the actual diffusion through the polymer matrix can be slow. But, because of the depletion of some molecules from the packaged solution, the properties of the product are altered as in the case of direct permeation of the product through the polymer. This is especially true if the absorbed molecules are related to taste, odor, or flavor of the contacting food or beverage. This phenomenon is directly proportional to the barrier properties of the polymer in most cases.

The main use of high barrier polymers is packaging, especially for foods and beverages, as a replacement for glass and metal containers. Light weight, nonshatterability, ease of disposal by incineration, and potentially lower costs are the forces behind the increasing popularity of barrier plastics. To be a successful food-and-beverage packaging material, the polymer must resist absorption from dilute solutions, retain carbon dioxide, protect food from oxygen, be durable, and have good creep strength, clarity, packaging processability, antistatic properties, and general chemical resistance (see Table 2).

The high nitrile polymers are the most interesting of the barrier polymers to be introduced. The permeation of any high nitrile polymer depends upon the level of nitrile, the type of nitrile, and the amount and type of comonomer and the presence of additives. Although the amount of nitrile is controlling, the comonomer can have significant barrier effects. For instance, whereas a 70:30 acrylonitrile–styrene copolymer

Table 1. Permeability Properties of High Barrier Polymers

Polymer	Polymer class	Permeation rates		
		Oxygen[a]	Carbon dioxide[a]	Water[b]
poly(vinylidene chloride)	halogenated	0.4	1.2	7.9
Lopac[c]	nitrile	3.9	12	200
Barex	nitrile	4.3	12	240
Cycopac[d]	nitrile	4.3	16	200
Saran wrap	halogenated	5.1	18	20
epoxy (bisphenol A; amine cure)	thermoset	12	35	160
Kel-F (polychlorotrifluoro-ethylene)	halogenated	13	47	12
Trogamid T	polyamide	18	47	205
Kynar [poly(vinylidene fluoride)]	halogenated	18	59	39
poly(ethylene terephthalate)	polyester	20–39[e]	47–79[e]	80–160[e]
nylon-6,9; nylon-6,10	polyamide	22	47	240
phenoxy [poly(phenylene oxide)]	aromatics	28	59	180
poly(vinyl chloride)	halogenated	31–59[f]	79–157[f]	80–120[f]

[a] At 23°C (100% rh), $(m^3 \cdot m)/(m^2 \cdot d \cdot PPa)$. To convert PPa to bar, multiply by 10^{10}.

[b] $kg \cdot cm/(im^2 \cdot d)$ at 38°C (100% rh).

[c] Acrylonitrile (70%)–styrene copolymer used for manufacturing Monsanto Cycle-Safe container.

[d] A similar polymer, Vicobar (DuPont), is no longer made. Vicobar had similar barrier properties.

[e] Depends on exact level of crystallinity and orientation.

[f] Depends on exact compound formulation.